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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 729,454	12/04/2000	Amy W. Lasck	PC-0028 US	6223

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/29/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/729,454

Applicant(s)

LASEK ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-37 is/are pending in the application.
- 4a) Of the above claim(s) 22, 23, 29, 30, and 32-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24, 27, 28, 31 and 37 is/are rejected.
- 7) ☒ Claim(s) 25 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Seq alignment*

DETAILED ACTION

Election/Restrictions

The prosecution history indicates applicant elected group I drawn to DNA, with species SEQ ID NO:1 (SEQ ID NO:1 is not a DNA, but protein) with traverse (see Paper NO:5).

Applicant cancelled all previously examined claims and presently new claims 22-37 are pending. Claims 22, 23 drawn to proteins (group VI in the restriction, Paper No. 4). See Paper No. 4 why claims 22 and 23 are different invention. Claims 32-37, drawn to method of using either the various nucleic acid or the various proteins/fragments are different inventions because they are classified in different classes and subclasses and the examined product (DNA) as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)) such as making antibody. Claims 22, 23, 29, 30, and 32-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Request for rejoining of the claims drawn to method of using of the elected product is noted. Process claims that include all the limitations of the allowable product will be rejoined when the product is allowable.

This application contains claims 22, 23, 29, 30, and 32-36 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 24-28, 31, and 37 are examined on merits.

Claim Rejections - 35 USC § 112

Rejection of the claim under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is moot** because the claim is cancelled.

Rejection of claims under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is withdrawn** because applicant's argument is persuasive.

Claims 24, 27, 28, and 31 **are rejected** for reason of record under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention. The written description rejection is applied to new claims 24, 27, 28, and 31. Applicant argues that one in skilled in the art would recognize naturally-occurring variants. This argument is not persuasive because it is clear from the prosecution history that applicant is claiming the allelic variants that the specification do not describe what the chemical structure look like.

Claim Rejections - 35 USC § 102

The new claims 24, 27, and 28 are rejected for reason of record under 35 U.S.C. **102(b)** as being anticipated by Boll et al (IDS, 1993, J. Biol. Chem. vol. 268, pages 12901-12911).

This rejection is based on the Office interpretation (note rejection of the instant claim under 35 U.S.C. 112, second paragraph below) of the claim being drawn to polynucleotide encoding any 5 consecutive amino acid sequence from the specifically recited fragment. Further, claim 24 depends on claim 22 which recites "an immunogenic portion" of a polypeptide consisting of the various recited fragments. The specification at page 12, lines 13 to 16 says that "antigenic epitopes extend from" the various recited fragments, which suggests that an antibody could be generated from any immunogenic portion from the specially recited fragments in claim 22.

Applicant argues that the amended claim is not anticipated by the art of record but this argument is not persuasive because Boll et al teach polynucleotide sequence that meets the limitation of the instant claim. See Fig. 3 along with the previously provided sequence alignment.

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Rejection of claims under 35 U.S.C. **102(b)** as being anticipated by NCBI accession number A1833131 (7-13-1999) **is withdrawn** because the amended claims are no longer anticipated by NCBI accession number A1833131 (7-13-1999).

NEW GROUNDS OF REJECTION

Specification

The amendment filed 3-4-2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the specification as originally filed does not say Donor 4097 is diagnosed with associated metastatic colon cancer. Applicant argues that the specification at Table 5 and page 11 lines 25-28 has support for the amendment but the specification as originally filed does not have the support. The information in Exhibit A was not disclosed in the specification as originally filed. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claims 24 and 25 are objected to because of the following informalities: they depend on claims drawn to non-elected invention. Appropriate correction is required. For the purpose of this Office action, all the limitations in claims 22 and 23 will be included in the examination of claims 24 and 25. However, this treatment does not relieve applicant the burden of responding this objection.

Claim Rejections - 35 USC § 112

Claims 24, 27, 28 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is confusing for two reasons. First, it is not clear what is the metes and bounds of an isolated polynucleotide encoding "an immunogenic portion of a polypeptide comprising..." The instant claim depends on claim 22 which, recites "an

immunogenic portion" of a polypeptide consisting of the various recited fragments. The specification at page 12, lines 13 to 16 says that "antigenic epitopes extend from" the various recited fragments, which suggests that an antibody could be generated from any immunogenic portion (any 5 consecutive amino acid sequence) from the specially recited fragments in claim 22. Second, it is not clear which limitation "comprising" or "consisting" controls the scope of the claims. This rejection affects the dependent claims. For the purpose of this Office action, the Office will assume an immunogenic portion is any 5 consecutive amino acid sequences from the specific fragments. However, this treatment does not relieve applicant the burden of responding this rejection.

Claim 37 is confusing because it is not clear which limitation "comprising" or "consisting" controls the scope of the claims. For the purpose of this Office action, the Office will assume that the any polynucleotide comprising the specific fragment recited in claim 37 a) and b) meets the limitation of the instant claim. However, this treatment does not relieve applicant the burden of responding this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 24 and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by GenEmbl accession number AK000134 (22-Feb-2000).

This rejection is based on the Office's interpretation of the claims being drawn to polynucleotide encoding "the immunogenic portion" from amino acid 66 to 90 of SEQ ID NO:1 (claim 24) and a polynucleotide comprising nucleotide 170 to nucleotide 220 of SEQ ID NO:3 (claim 37). GenEmbl accession number AK000134 (22-Feb-2000) teaches polynucleotide sequence identical to nucleotide 1 to 528 of SEQ ID NO:3. See the sequence alignment.

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Conclusion


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800 1600

Misook Yu
May 27, 2003